

EXHIBIT B

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE: Bair Hugger Forced Air Warming
Products Liability Litigation

Case No. 0:16-cv-04159 (JNE/DTS)

This Document Relates to All Actions.

**PLAINTIFF'S SUPPLEMENTAL
EXPERT REPORT**

PLAINTIFF(S)

ADA TROMBLEY

VS.

**3M COMPANY,
a Delaware Corporation**

Plaintiff herewith submits the supplemental report of Yadin David, Ed.D., P.E., C.C.E. in order to reserve all rights and preserve the record in this and other cases in this MDL.



Supplemental Report

Yadin David, Ed.D., P.E., C.C.E.

This report sets forth additional information relating to several specific products which are consistent with the alternative design concepts I discussed in my initial report. My initial report outlined several design concepts and provides an example of each. This supplemental report outlines further examples of commercially available patient warming alternatives. The below list is not meant to be exhaustive but examples of active and passive warming devices that are a reasonable and safer alternative design used for patient warming.

1. Kanmed WarmCloud

The Kanmed WarmCloud, “a pressure relieving warm air mattress, is designed to be used pre, per and post operatively.”¹ Much like the Berchtold TableGard discussed in my initial report, the Kanmed WarmCloud uses forced-air to achieve underbody heating without exhausting air around the operating site.

The one major difference between the TableGard and WarmCloud is that the WarmCloud features a “a single use Warm Air mattress.”² Like in the Bair Hugger, this lowers the initial cost but adds the cost of a disposable. As such, the overall economic feasibility of the device is similar to the Bair Hugger. In May 2008, a randomized trial was published comparing the Kanmed WarmCloud with the Bair Hugger.³ The study found that the devices maintained similar temperatures, with the WarmCloud being more effective. The authors concluded that the “WarmCloud device is optimally suited to maintain core normothermia for longstanding procedures.”⁴

2. Inditherm Warming Blanket

I have reviewed guidance documentation created in August 2011 from the National Institute for Health and Clinical Excellence (NICE) endorsing the use of the Inditherm patient warming device, a design incorporating the use of resistive heating blanket. According to NICE, “the Inditherm patient warming mattress uses flexible, carbon-based conductive polymer technology that aims to generate a uniform, direct heating surface. It is a low voltage, reusable device that does not require disposable products. The temperature of the mattress is maintained by

¹ TAB 1 - Kanmed WarmCloud User Manual.

² TAB 2 - Kanmed WarmCloud Brochure, p. 2.

³ TAB 3 - Perioperative temperature management. Comparison of a forced air warming device and a dynamic air mattress device in plastic surgery. European Journal of Anaesthesiology, May 2008.

⁴ *Id.*

a control unit and is user-selectable.”⁵ The mattress is designed using “a viscoelastic foam pad which is designed to mould itself to the shape of the patient.”⁶ Numerous published studies show that the Inditherm mattress achieves comparable temperature results as forced-air warming.⁷ In addition, the NICE researchers considered the risk of infection:

Mindful of possible transmission of infection, the Committee asked the expert advisers and the manufacturer about cleaning the Inditherm mattress between patients. It was told that the mattress is cleaned in the same way as the normal operating table mattress.⁸

According to NICE, “the annual cost of the Inditherm patient warming system in the cost model was approximately £1300 per operating theatre.”⁹ Because it does not use disposables, “the average annual cost saving associated with use of the Inditherm patient warming system is estimated to be £9800 per theatre.”¹⁰

3. LMA PerfecTemp

The LMA PerfecTemp “is an underbody resistive warming system that combines servocontrolled underbody warming with viscoelastic foam pressure relief.”¹¹ In 2011, a clinical trial was published comparing the PerfecTemp to the Bair Hugger. Researchers found that “core temperatures were no different, and significantly noninferior, with underbody resistive heating in comparison with upper-body forced-air warming.”¹² I have also reviewed a PowerPoint presentation created by the Department of Outcomes Research at the Cleveland Clinic. According to the Cleveland Clinic, “the blanket uses an antimicrobial / antifungal fabric cover,”¹³ and they also noted that it presents “no chance of potential increase risk of contamination.”¹⁴ The researchers noted that the device “pays for itself, by significant reduction of disposables,” and that it “can generate hundreds of thousands of dollars in savings.”¹⁵ Finally, the Cleveland Clinic’s testing showed that “PerfecTemp warms more surface area than forced air.”¹⁶

⁵ TAB 4 - National Institute for Health and Clinical Excellence Guidance Document on Inditherm, p. 5.

⁶ *Id.*

⁷ *Id.* at p. 6-9.

⁸ *Id.* at p. 11.

⁹ *Id.* at p. 12.

¹⁰ *Id.*

¹¹ TAB 5 - A Randomized Comparison of Intraoperative PerfecTemp and Forced-Air Warming During Open Abdominal Surgery. *Anesthesia & Analgesia*, June 2011.

¹² *Id.*

¹³ TAB 6 - Cleveland Clinic PowerPoint on PerfecTemp, p. 6.

¹⁴ *Id.* at p. 10.

¹⁵ *Id.* at p. 11.

¹⁶ *Id.* at p. 13.

4. **Barrier Easy Warm**

The Barrier Easy Warm is “a disposable, active self-warming blanket.”¹⁷ In 2014, the Easy Warm blanket was subject to a multicenter study on its effectiveness. The authors described the blanket as follows:

The blanket has pouches with warmers containing iron, which is activated when exposed to ambient air. The blanket remains active at an average temperature of 44°C for a minimum of ten hours. The blanket is easy to use, requires no electricity and can be used through the entire perioperative period.¹⁸

The researchers found “a significantly lower incidence of hypothermia intraoperatively and postoperatively” when using the Easy Warm blanket.¹⁹ Although the product was launched in 2014,²⁰ the technology for air-activated warmers using iron has existed for nearly 100 years, and consumer products using this technology, such as hand warmers commonly used in the cold outdoors such as camping, have been widely available for decades.

5. **Reflective Blankets**

Comparable patient warming goal can also be achieved by the operative use of common reflective blankets following pre-warming. In July 2016, researchers conducted a randomized, controlled trial comparing the Bair Hugger and reflective blankets. The study “showed that after active prewarming, intraoperative passive warming with reflective thermal blankets was as effective as active warming with Bair Hugger blankets in hip and knee arthroplasty surgeries.”²¹ The authors noted that “reflective blankets do not disrupt airflow and therefore have no potential for this increase in surgical site infection.”²² The use of common reflective blankets “eliminates any laminar airflow disruption” and “eliminates the transfer of potential pathogenic organisms by the device.”²³ These blankets have long been available, as the first reflective blankets were developed by NASA in the 1964.²⁴

6. **Cotton Blankets**

Cotton blankets (passive warming) have been used by the medical community prior to the development of active warming products such as the Bair Hugger. Studies have shown that cotton

¹⁷ TAB 7 - Reduced hypothermia and improved patient thermal comfort by perioperative use of a disposable active self-warming blanket: A randomized multicenter trial. Presented at: 67th Annual Postgraduate Assembly in Anesthesiology; 2013 Dec 13-17.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ TAB 8 - Barrier Easy Warm Press Release.

²¹ TAB 9 - Reflective Blankets Are as Effective as Forced Air Warmers in Maintaining Patient Normothermia During Hip and Knee Arthroplasty Surgery, *The Journal of Arthroplasty*, July 2016.

²² *Id.*

²³ *Id.*

²⁴ See <https://www.nasa.gov/offices/oct/40-years-of-nasa-spinoff/emergency-blankets>

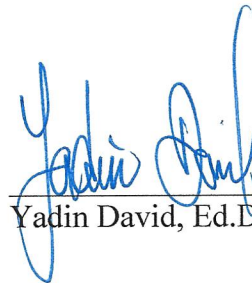
blankets are just as effective as active warming products for surgeries that last less than 2 hours similar to the type of surgeries that are the subject of this litigation. Furthermore, since cotton blankets do not use convective warming but are conductive warming devices, there are no risks such as disruption of the airflow or the increase in pathogens over the surgical site that are present during the use of the Bair Hugger.

7. Pre-warming

Prewarming patients for 30 to 60 minutes prior to induction of anesthesia is an effective and safer alternative design to prevent hypothermia in patients undergoing surgeries of less than 2 hours.²⁵ Since 2001, studies have shown that pre-warming was just as effective as intraoperative warming for surgeries lasting less than two hours.²⁶ Since pre-warming is performed outside the operating room, there are no risks associated with pre-warming that are evident in the Bair Hugger system.²⁷ Pre-warming does not disrupt the airflow in the operating room and does not increase pathogens over the sterile field.

CONCLUSION

It is my opinion to a reasonable degree of biomedical engineering certainty that each of these devices are economically feasible, and that each qualifies as a reasonable safer alternative design to the Bair Hugger in achieving patient warming during orthopedic surgery. Each of these alternative designs eliminates the risk of airborne infection and achieves comparable core temperatures.



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²⁵ J. Andrzejowski, J. Hoyle, G. Eapen, D. Turnbull; Effect of prewarming on post-induction core temperature and the incidence of inadvertent perioperative hypothermia in patients undergoing general anaesthesia, *BJA: British Journal of Anaesthesia*, Volume 101, Issue 5, 1 November 2008, Pages 627–631, <https://doi.org/10.1093/bja/aen272>

²⁶ Melling, A.C., Ali, B., Scott, E.M. and Leaper, D.J., 2001. Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomised controlled trial. *The Lancet*, 358(9285), pp.876-880.

²⁷ A.V. Duren; Prewarming, Arizant Healthcare, January 2005, p. 3MBH00297660.